

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

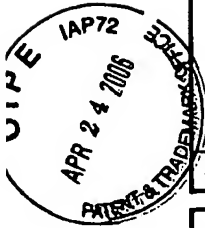
**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known

| | |
|----------------------|----------------|
| Application Number | 10/811,343 |
| Filing Date | March 26, 2004 |
| First Named Inventor | Cook, W. |
| Art Unit | 1651 |
| Examiner Name | Witz, Jean C. |
| Attorney Docket No. | 003433-000492 |

**U.S. PATENT DOCUMENTS**

| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Application of Cited Document | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear |
|-----------------------|--------------------------|--|--------------------------------|--|---|
| | | Number-Kind Code ² (If known) | | | |
| PP/ | | US- 2,172,903 | 08/23/1938 | Bowen, A. | |
| | | US- 3,562,820 | 02/16/1971 | Bernhard, B. | |
| | | US- 3,632,361 | 01/04/1972 | Battista, O | |
| | | US- 3,810,473 | 05/14/1974 | Cruz, et al. | |
| | | US- 4,292,972 | 10/06/1981 | Pawelchak, et al. | |
| | | US- 4,347,234 | 08/31/1982 | Wahlig, et al. | |
| | | US- 4,421,947 | 12/20/1983 | Kyle, J. | |
| | | US- 4,578,067 | 03/23/1986 | Cruz, Jr. M. | |
| | | US- 4,606,337 | 08/19/1986 | Zimmermann, et al. | |
| | | US- 4,902,508 | 02/20/1990 | Badylak, et al. | |
| | | US- 4,948,540 | 08/14/1990 | Nigam, A. | |
| | | US- 4,950,483 | 08/21/1990 | Ksander, et al. | |
| | | US- 4,956,178 | 09/11/1990 | Badylak, et al. | |
| | | US- 4,970,298 | 11/13/1990 | Silver, et al. | |
| | | US- 4,994,084 | 02/19/1991 | Brennen, H. | |
| | | US- 5,028,695 | 07/02/1991 | Eckmayer, et al. | |
| | | US- 5,141,747 | 08/25/1992 | Scholz, M. | |
| | | US- 5,206,028 | 04/27/1993 | Li, S. | |
| | | US- 5,219,576 | 06/15/1993 | Chu, et al. | |
| | | US- 5,275,826 | 01/04/1994 | Badylak, et al. | |
| | | US- 5,281,422 | 01/25/1994 | Badylak, et al. | |
| | | US- 5,336,616 | 08/09/1994 | Livesey, et al. | |
| | | US- 5,372,821 | 12/13/1994 | Badylak, et al. | |
| | | US- 5,397,352 | 03/14/1995 | Burres, S. | |
| | | US- 5,445,833 | 08/29/1995 | Badylak, et al. | |
| | | US- 5,446,462 | 08/29/1995 | Cleveland, A. | |
| | | US- 5,451,406 | 09/19/1995 | Lawin, et al. | |
| | | US- 5,457,093 | 10/10/1995 | Cini, et al. | |
| | | US- 5,460,962 | 10/24/1995 | Kemp, P. | |
| | | US- 5,480,424 | 01/02/1996 | Cox, J. | |
| | | US- 5,480,427 | 01/02/1996 | Kelman, et al | |

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| | | | | | |
|---|---|----|---|--------------------------|----------------|
| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Complete if Known | |
| | | | | Application Number | 10/811,343 |
| | | | | Filing Date | March 26, 2004 |
| | | | | First Named Inventor | Cook, W. |
| | | | | Art Unit | 1651 |
| | | | | Examiner Name | Witz, Jean C. |
| Sheet | 2 | of | 4 | Attorney Docket No. | 003433-000492 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|-----------------------|---|--------------------------------|--|---|
| Examiner Initials* | Cite No. ¹ | Document Number Number-Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear |
| PP/ | | US- 5,489,022 | 02/06/1996 | Baker, B. | |
| | | US- 5,489,261 | 02/06/1996 | Franzblau, et al. | |
| | | US- 5,498,420 | 03/12/1996 | Mentrup, et al. | |
| | | US- 5,489,022 | 02/06/1996 | Baker, B. | |
| | | US- 5,489,261 | 02/06/1996 | Franzblau, et al. | |
| | | US- 5,498,420 | 03/12/1996 | Mentrup, et al. | |
| | | US- 5,501,706 | 03/26/1996 | Arenberg, I. | |
| | | US- 5,514,181 | 05/07/1996 | Light, et al. | |
| | | US- 5,516,395 | 05/14/1996 | Anhauser, et al. | |
| | | US- 5,520,925 | 05/28/1996 | Maser, F. | |
| | | US- 5,531,786 | 07/02/1996 | Perry, et al. | |
| | | US- 5,531,791 | 07/02/1996 | Wolfenbarger, L. | |
| | | US- 5,554,389 | 09/10/1996 | Badylak, et al. | |
| | | US- 5,565,210 | 10/15/1996 | Rosenthal, et al. | |
| | | US- 5,567,806 | 10/22/1996 | Abdul-Malak, et al. | |
| | | US- 5,571,181 | 11/05/1996 | Li, S. | |
| | | US- 5,607,476 | 03/04/1997 | Prewett, et al. | |
| | | US- 5,607,590 | 03/04/1997 | Shimizu, Y. | |
| | | US- 5,641,518 | 06/24/1997 | Badylak, et al. | |
| | | US- 5,645,860 | 07/08/1997 | Knapp, et al. | |
| | | US- 5,695,998 | 12/09/1997 | Badylak, et al. | |
| | | US- 5,711,969 | 01/27/1998 | Patel, et al. | |
| | | US- 5,755,791 | 05/26/1998 | Whitson, et al. | |
| | | US- 5,762,966 | 06/09/1998 | Knapp, et al. | |
| | | US- 5,782,914 | 07/21/1998 | Schankereli, K. | |
| | | US- 5,866,414 | 02/02/1999 | Badylak, et al. | |
| | | US- 5,885,619 | 03/23/1999 | Patel, et al. | |
| | | US- 5,955,110 | 09/21/1999 | Patel, et al. | |
| | | US- 6,099,567 | 08/08/2000 | Badylak, et al. | |
| | | US- 6,206,931 | 03/27/2001 | Cook, et al. | |
| | | US- 6,475,232 | 11/05/2002 | Babbs, et al. | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| | | | | | |
|---|---|----|---|--------------------------|----------------|
| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Complete if Known | |
| | | | | Application Number | 10/811,343 |
| | | | | Filing Date | March 26, 2004 |
| | | | | First Named Inventor | Cook, W. |
| | | | | Art Unit | 1651 |
| | | | | Examiner Name | Witz, Jean C. |
| Sheet | 3 | of | 4 | Attorney Docket No. | 003433-000492 |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|-----------------------|---|--|--------------------------------|--|--|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | Publication Date MM-DD-YYYY | Name of Patentee or Application of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Country Code ³ -Number ⁴ - Kind Code ⁵ (if known) | | | | |
| /PP/ | | WO 95/22611 | | 08/24/1995 | The Regents of the University of Michigan | <input type="checkbox"/> |
| /PP/ | | WO 96/24661 | | 08/15/1996 | Purdue Research Foundation, et al. | <input type="checkbox"/> |
| /PP/ | | WO 96/25179 | | 08/22/1996 | Purdue Research Foundation, et al. | <input type="checkbox"/> |
| /PP/ | | WO 96/31157 | | 10/10/1996 | Organogenesis, Inc. | <input type="checkbox"/> |
| /PP/ | | WO 96/32146 | | 10/17/1996 | Advanced Cytometrix, Inc. | <input type="checkbox"/> |
| /PP/ | | WO 98/22158 | | 05/28/1998 | Cook Biotech, Inc.; Med Institute, Inc. | |
| /PP/ | | WO 98/25636 | | 06/18/1998 | Purdue Research Foundation | |
| /PP/ | | WO 98/25637 | | 06/18/1998 | Purdue Research Foundation | |
| /PP/ | | WO 98/26291 | | 06/18/1998 | Purdue Research Foundation | |
| /PP/ | | WO 00/32250 | | 06/08/2000 | Cook Biotech, Inc. | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| | | | | | |
|---|---|----|---|--------------------------|----------------|
| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Complete if Known | |
| | | | | Application Number | 10/811,343 |
| | | | | Filing Date | March 26, 2004 |
| | | | | First Named Inventor | Cook, W. |
| | | | | Art Unit | 1651 |
| | | | | Examiner Name | Witz, Jean C. |
| Sheet | 4 | of | 4 | Attorney Docket No. | 003433-000492 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|--------------------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published | T ² |
| /PP/ | | American National Standard, ANSI/AAMI 10993-1:1994. "Biological Evaluation of Medical Devices—Part 1: Guidance on Selection of Tests". Association for the Advancement of Medical Instrumentation. pp. 9-17. | <input type="checkbox"/> |
| /PP/ | | BLOCK, S. "Peroxygen Compounds", <i>Disinfection, Sterilization and Preservation</i> , 5 th Edition 2001. pp. 185-204. Lippincott Williams & Wilkins, Philadelphia, PA. | <input type="checkbox"/> |
| /PP/ | | CLARKE, K.M., et al. "Intestine Submucosa and Polypropylene Mesh for Abdominal Wall Repair in Dogs". <i>The Journal of Surgical Research</i> . Jan. 1996. Vol. 60, No. 1. pp. 107-114. | <input type="checkbox"/> |
| /PP/ | | DENTON, F.W., "Chlorhexidine", <i>Disinfection, Sterilization and Preservation</i> , S. Block, editor, 5 th Edition 2001. pp. 321-336. Lippincott Williams & Wilkins, Philadelphia, PA. | <input type="checkbox"/> |
| /PP/ | | "Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices". Dec. 1997. Center for Drug Evaluation and Research, Center for Biologic Evaluation and Research, Center for Devices and Radiological Health, and Center for Veterinary Medicine. | <input type="checkbox"/> |
| /PP/ | | KROPP, B.P., et al. "Experimental Assessment of Small Intestinal Submucosa as a Bladder Wall Substitute". <i>Urology</i> . Sept. 1995. Vol 46, No. 3. pp. 396-400. | <input type="checkbox"/> |
| /PP/ | | KROPP, B.P., et al. "Regenerative Urinary Bladder Augmentation Using Small Intestinal Submucosa: Urodynamic and Histopathologic Assessment in Long-Term Canine Bladder Augmentations". <i>The Journal of Urology</i> . June 1996. Vol. 155, No. 6. pp. 2098-2104. | <input type="checkbox"/> |
| /PP/ | | PREVEL, C.D., et al. "Small Intestinal Submucosa: Utilization for Repair of Rodent Abdominal Wall Defects". <i>Annals of Plastic Surgery</i> . Oct. 1995. Vol. 35, No. 4. pp. 374-380. | <input type="checkbox"/> |
| /PP/ | | PREVEL, C.D., et al. "Small Intestinal Submucosa: Utilization as a Wound Dressing in Full-Thickness Rodent Wounds". <i>Annals of Plastic Surgery</i> . Oct. 1995. Vol. 35, No. 4. pp. 381-388. | <input type="checkbox"/> |

| | | | |
|--------------------|-----------------|-----------------|------------|
| Examiner Signature | /Paul Prebilic/ | Date Considered | 04/03/2007 |
|--------------------|-----------------|-----------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here if English language Translation is attached.